

ARGUMENTS FOR PATENTABILITY

The amendments to the specification and claims overcome the Examiner's objections and rejections.

The objection to claim 1 has been overcome by canceling claim 1 and amending claim 4 to use the term, "comprising", in place of the original term, "consisting of".

The indefiniteness of claim 4 has been corrected by correcting the language to specify that the tubular nail includes the nailhead, a plurality of thin rods and a node intermediate the proximal area of the rods and the terminal sections of the rods. The term, "functional combination" has been incorporated into the specification, and claim 3 has been clarified by including adjectives modifying the term, "hole", specifying either the axial hole or a screw hole. The terminal part of claim 3 has been deleted and incorporated in new claim 5. In addition, claim 3 has been amended to set forth that the claim is directed to a combination of the intramedullary nail with a template. In addition, the specification has been amended to provide antecedent basis for all of the terms in claim 4.

Before discussing the Examiner's rejection of all of the claims on the basis of 35 U.S.C. §102 or 35 U.S.C. §103, it is appropriate to review the impetus behind the development of the subject invention. An intramedullary requires certain characteristics which are not required by blind fasteners to be used in masonry construction. Although both the intramedullary nail and the blind fastener are to be employed for joining two separate pieces, the intramedullary nail has certain objectives which are not required in a blind fastener. For an optimal consolidation of the bone callus, the intramedullary nail should have the following characteristics:

It must ensure that a lateral pressure against the walls of the hole was introduced (in this case, the spinal canal) so as to prevent the components from leaving the channel which includes the medullary cavity. Resistance to pullout is not unique to intramedullary nails, but is present in the Summerlin blind fasteners.

More significantly, the intramedullary nail must create a pressure between two foci of fracture so that the resulting connection is stable against rotation, and in case of a fracture, to insure that the two bone fragments are properly aligned. For example, in the case of the femur, if one of the fragments deviates from the other, there would be an alteration of the biomechanical axis of travel causing problems with walking. In particular, the present invention focused on solving the problem in the implantation of the intramedullary nail to insure stability and to avoid the rotating. In the prior art, screws were used at both the distal

and the proximal ends of the nail to anchor the nail properly. In the prior art, it was necessary to use guidance x-ray with the problems that this creates, in particular the problem of exposure of the surgeon's hands to x-ray radiation.

Applicants' invention provides an interlocking of the two bone fragments without the need to use an x-ray in the vicinity of the surgeon's hands. The present invention provides the lock by advancing the nail through the channel into the medullary cavity while firmly anchoring the proximal end of the nail in the bone structure. This positive locking of the proximal end of the nail is accomplished by the radial fins in the support, as claimed in claim 4 and, more specifically, as claimed in claim 2. It is noted that the anchoring of the intramedullary nail to the bone is accomplished prior to actuation of the nail which entails the application of a torque to the screw 12. As shown in Figs. 1 and 2, the fin 9 is radial to the longitudinal axis of the intramedullary nail providing the greatest resistance to rotation about that axis.

With the intramedullary nail inserted into the channel of the bone, the nail is actuated to cause the probe to first displace the free ends of the terminal sections of the rods to properly engage the bone fragments. Further actuation of the probe expands the proximal sections of the rods against the walls of the channel to firmly lock the two bone fragments together. It should be noted that the proximal sections of the rods of Applicants' device extend axially of the tubular nail so that when they are expanded outwardly by the probe engaging the node, there is no force tending to rotate the rods, as would be the case with the oblique struts 21 of the Summerlin patent. It should also be noted that the present invention is not for the connection of a sheet member 37 to a wall surface 34, but, rather, is a device to interlock two fragments of a long bone to enable healing of the fracture in the absence of deleterious relative displacement of the fragments.

Claim 4 was rejected under 35 U.S.C. §102 as being anticipated by the Summerlin blind fastener. The Examiner describes the Summerlin blind fastener using terms from Applicants' claim 4 which are not applicable to the Summerlin disclosure. Summerlin does not disclose an intramedullary nail, nor is it specially designed to secure and immobilize fractures in long bones. More importantly, the blind fastener of Summerlin does not comprise the functional combination of a support, a tubular nail and a probe, the tubular nail and probe having a length no greater than the distance between the proximal and distal ends of the a long bone. There is no support adapted to engage the proximal end of the long bone and anchor the tubular nail against rotation. The Summerlin patent does not

have a plurality of thin rods of considerable length as suggested by the Examiner by referring to the longitudinal struts 21 spaced circumferentially around the sleeve and mutually spaced apart by voids 22. When Applicants claim a plurality of thin rods of considerable length, they are not claiming struts and voids. Thus, Applicants' claims are not anticipated by the Summerlin patent, as required by §102.

The Examiner rejected claims 2 and 3 as being obvious in view of Summerlin. Claim 2 sets forth that the support has a stepped axial hole for attachment to the nailhead and a fin with screw holes for screwing the support to the bone. The fin is oriented radial to the longitudinal axis of the intramedullary nail. The structural components of claim 2 enable the support to be the only element that is fixed to the bone prior to actuation of the nail. It should be noted that in the Summerlin patent, the steel shell 11 is anchored in place by actuation of the device to displace the bolt 12 and the frustoconical wedge 14 into the interior of the arms 17 to anchor the shell to the cement hole in which it is placed. Thus, the Summerlin patent does not teach or suggest a structure which enables, much less require, a tubular nail to be anchored prior to actuation of the device. Thus, claim 2 defines a structure which is neither taught nor suggested by the Summerlin patent.

Claim 3 is now directed to the combination of a support with a template. The Summerlin patent does not teach such a combination. Since claim 3 is dependent upon claim 2, claim 3 is properly patentable over Summerlin for the reasons set for above in connection with claim 2 and for the absence of disclosure of a template in combination with a nail.

Claim 5 is a new claim directed to the feature in the latter part of original claim 3 and is a more specific definition of the probe defined in claim 4. Accordingly, claim 5 is believed properly patentable along with claim 4.

Grant of European Patent No. EP 1 690 507 B1 was published December 17, 2008 in Bulletin 2008 (51), and grant of a US patent is appropriate.